the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

(b) *Classification*. Class II.

Subpart F—Therapeutic Devices

§ 872.5410 Orthodontic appliance and accessories.

(a) *Identification*. An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38799, July 25, 2001]

§ 872.5470 Orthodontic plastic bracket.

(a) *Identification*. An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

(b) *Classification*. Class II.

§ 872.5500 Extraoral orthodontic headgear.

(a) *Identification*. An extraoral orthodontic headgear is a device intended for use with an orthodontic appliance to exert pressure on the teeth from outside the mouth. The headgear has a strap intended to wrap around the patient's neck or head and an inner bow portion intended to be fastened to the orthodontic appliance in the patient's mouth.

(b) *Classification*. Class II.

§ 872.5525 Preformed tooth positioner.

(a) *Identification*. A preformed tooth positioner is a plastic device that is an impression of a perfected bite intended to prevent a patient's teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38799, July 25, 2001]

§ 872.5550 Teething ring.

(a) *Identification*. A teething ring is a divice intended for use by infants for medical purposes to soothe gums during the teething process.

(b)(1) *Classification*. Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

(2) Class II if the teething ring contains a fluid, such as water.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994]

§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

(a) *Identification*. Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

(b) *Classification*. Class II (special controls). The special control for these devices is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA.''

[67 FR 68512, Nov. 12, 2002]